Substitute for form	n 1449A/PTO			Complete	e if Known
IPE				Application No.	09/760,120
• •	FORMATION D	nisci ns	HRF	Filing Date:	January 12, 2001
2 2 2002	TATEMENT BY	ADDITO	ANT	First Named Inventor	Sarah S. Bacus
ω <sub>ω</sub> ,	IAIEWENI DI	APPLIC	ANI	Group Art Unit	1641
AUEMARK S	(use as many sheets	s as necessa	ry)	Examiner Name	
Sheet	1	of	2	Attorney Docket No.	01-033

					U.S	. PATENT DOCUMEN	TS		
Examiner	Cite	U.S.	Patent D	ocument			Date of Publication of	Pages, Columns, Lines Where Relevant Passages on Figures Appe	
Initials*	No. 1	Num	ber	Kind Code <sup>2</sup> (if known)	Name	of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY		
88.	ï	6,165	,734	-		Buckwald et al. Gar	ini et al. —		П
OX.		5,998	,151			Eisher et al Vohn	nston et al. =		$\mathbf{C}$
28		5,514	,554			Sarah Bacus		ER 8	П
88		5,202	,931			Sarah Bacus		2002 1600/2	_<
								90/2	П
					FORE	IGN PATENT DOCUM	ENTS	900	
Examiner	Cite	Foreign Patent Documer					Date of Publication of	Pages, Columns, Lines	
Initials*	No.	Office <sup>3</sup>	Nun	abor <sup>a</sup> l	Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Figures Appear	T <sup>6</sup>
81		wo	00/2	3799	Α	Steven Smith			
88		EP	0378	3 383		Univ. Arizona			
<del>-</del>		wo	93 0	3741		Yeda Res. & Dev.			

		OTHER DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		Van Diest et al., Analytical Cellular Pathology, vol. 3, no. 4, 1991, pages 195-202.	yls
Sog		Bacus et al., Archives of Pathology and Laboratory Medicine, vol. 114, no. 2, 1990, pages 164-169	
88		Bacus et al., American Journal of Pathology, vol. 137, no.1, July 1990, pages 103-	

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to compete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC. 20231

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English translation is attached.

Substitute for form	1449A/PTO	-		Complete if Known			
OIPA				Application No.	09/760,120		
luk)	FORMATION	DISCLOS	URF	Filing Date:	January 12, 2001		
MAR 2 2 2002	ATEMENT BY	V D D I I C	ANT	First Named Inventor	Sarah S. Bacus		
	AIEWENT DI	AFFLIO	AILI	Group Art Unit	1641		
& Man - 10 QV	(use as many sheet	s as necessa	ry)	Examiner Name			
Sheet	2	of	2	Attorney Docket No.	01-033		

		OTHER DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
87		Van Diest et al., Analytical Cellular Pathology, vol. 3, no. 4, 1991, pages 195-202.	
8/		Muss et al., 1994, N. Engl. J. Med. 330:1260-66	
QK		Kraus et al., 1989, Proc. Natl. Acad. Sci. U.S.A. 86:9193-97	R
4X		Mendelsohn, 1990, Semin. Cancer Biol. 1:339-44	Ö
28		Hancock et al., 1991, Cancer Res. 51:4575-80	
XX		Peles et al., 1991, EMBO J. 10:2077-86	¥
0 "		Peles et al., 1991, EMBO J. 10:2077-86  Peles et al., 1991, EMBO J. 10:2077-86  Peles et al., 1991, EMBO J. 10:2077-86	
28		Arteaga et al., 1994, Cancer Res., 54:3758-65	
88		Pietras et al., 1994, Oncogene 9:1829-38	
88		Cobleigh et al., 1999, J. Clin. Oncol. 17:2639-48	
		DiGiovanna, 1999, PPO Updates: Princ. Practice Oncol. 13:1-9	
		Shak, 1999, Semin. Oncol. 26:71-77	
		Sliwkowski et al., 1999, Semin. Oncol. 26.60-70	
84		Vincent et al., 2000, Cancer Chemother. Pharmacol. 45:231-38	
ZX/		Lowry et al., 1951, J. Biol. Chem. 193:265-275	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English translation is attached.

Substitute f	or form	1449A/PTO				Complete	
					Applica	ation No.	09/760,120 January 12, 2001
	INF	ORMATIC	N DISCI	OSURE E JOSO	Filing [	Date:	January 12, 2001
		ATEMENT		LICAKAT &	First N	amed Inventor	Sarah S. Bacus
	31	AICMENI	DIAPP	LICANT	roup /		Sarah S. Bacus
		(use as many	sheets as ned	1 ~	7	er Name	
Sheet		1		of 3	العال	y Docket No.	01-033
Onect				PATENT 8	7 / 1110/110	, 2001.01.10.	70
				U.S. PATENT DOC	UMENTS	<b>3</b>	5
xaminer	Cite	U.S. Patent Document				Date of Publication of	Pages, Columns, Lines
Initials*	No.	Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applic	Cited Document MM-DD-YYYY		Where Relevant Passages or Figures App
OX		6,165,734		Buckwald et al.	Garn	ni et al	
388		5,998,151		Fisher et al	Johns	ton et al	
RY		5,514,554		Sarah Bacus			
		5,202,931		Sarah Bacus		•	
D							
				FOREIGN PATENT D	OCUMEN	ITS	
Examiner	Cite	Foreign	Patent Documen			Date of Publication of	Pages, Columns, Lines Where Relevant

				FOREIC	GN PATENT DOCUME	NTS		
Examiner Cite No.	Cite	Foreign Patent Document				Date of Publication of	Pages, Columns, Lines	
	No. 1	Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Figures Appear	Т <sup>6</sup>
ХB		wo	00/23799	А	Steven Smith		>	
861		EP	0378 383		Univ. Arizona		3	
8		wo	93 03741		Yeda Res. & Dev.			

	OTHER DOCUMENTS NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>		

Examiner Signature	Bnilere	B-	Brhel	Date Considered	5/21/02
Signature		L-		Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to compete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC. 20231

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English translation is attached.

		OTHER ROCHMENTS MON PATENT LITERATURE ROCHMENTS	***	_
	<del></del>	OTHER DOCUMENTS NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.		문	T <sup>2</sup>
Stro	5.2	Arteaga et al., 1994, Cancer Res., 54:3758-65	9	A T X
08/	2007 P	Bacus et al., "Potential use of Image Analysis for the Evaluation of Cellular Predicting Factors for Therapeutic Response in Breast Cancers", Analytical and Quantitative Cytology and Histology, vol. 19 no. 4, August 1997, pages 316-328.	TER 1600	1 9 2004
88°	ATEMT &	Bacus et al., "HER-2/neu oncogene expression, DNA ploidy and proliferation index in breast cancer", Analytical and Quantitative Cytology and Histology", vol. 14, no. 6, 1992 pages 433-445.	2900	
81		Bacus et al., "HER-2/NEU Oncogene Expression and DNA Ploidy Analysis in Breast Cancer", American Journal of Pathology, vol. 114, no. 2, 1990, pages 164-169.		
88		Bacus et al., "HER-2/Neu oncogene expression and proliferation in breast cancer", American Journal of Pathology, vol. 137, no. 1- July 1990.		
88		Cobleigh et al., "Multinational Study of the Efficacy and Safety of Humanized Anti-HER2 Monoclonal Antibody in Women Who Have HER2-Overexpressing Metastati Breast Cancer That Has Progressed After Chemotherapy for Metastatic Disease", 1999, J. Clin. Oncol. 17:2639-48.	ic	
88		Hancock et al., "A Monoclonal Antibody against the c-erbB-2 Protein Enhances the Cytotoxicity of cis-Dianninedichloroplatinum against Human Breast and Ovarian Tumor Cell Lines",1991, Cancer Res. 51:4575-80.	2	
88		Kraus et al., "Isolation and Characterization of ERBB3, a third member of the ERBB/epidermal growth factor receptor family: Evidence for overexpression in a subset of human mammary tumors", 1989, Proc. Natl. Acad. Sci. U.S.A. 86:9193-97.		
88		Lowry et al., "Protein Measurement with the Folin Phenol Reagent", 1951, J. Biol. Chem. 193:265-275.		

Substitute for form 1449A/PTO Complete if Known

5/21/02

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English translation is attached.

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

P(use as many sheets as necessary)

Application No. 09/760,120

Filing Date: January 12, 2001

First Named Inventor Sarah S. Bacus

Group Art Unit 1641

Examiner Name

Attorney Docket No. 01-033

(	APR 1	5 2002 (a)	Ë	7
THE STATE OF THE S	<i>&gt;</i> ه	OTHER DOCUMENTS NON PATENT LITERATURE DOCUMENTS	田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田	19
Examiner Initials*	Cite No.	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	00062/009	2002~
98		Mendelsohn, "The epidermal growth factor receptor as a target for therapy with antireceptor monoclonal antibodies" 1990, Semin. Cancer Biol. 1:339-44.	0	
88		Muss et al., "c-erbB-2 Expression and Response to Adjuvant Therapy in Women with Node-Positive Early Breast Cancer",1994, N. Engl. J. Med. 330:1260-66.		
88		Peles et al., "Oncogenic Forms of the Neu/HER2 Tyrosine Kinase are Permanen Coupled to Phospholipase Cy", 1991, EMBO J. 10:2077-86.	tly	
88		Peles et al., "Isolation of the Neu/HER-2 Stimulatory Ligand: A 44 kd Glycoprotei That Induces Differentiation of Mammary Tumor Cells", 1992, Cell 69:205-16.	<u> </u>	
86		Pietras et al., "Antibody to HER-2/neu receptor blocks DNA repair after cisplatin i human breast and ovarian cancer cell", 1994, Oncogene 9:1829-38.	n	
88		Van Diest et al., "Quantitation of HER-2/neu oncoprotein overexpression in invas breast cancer by image analysis: a study comparing fresh and paraffin-embeddematerial", Analytical Cellular Pathology, vol. 3, no. 4, 1991, pages 195-202.		
88		Vincent et al., "Anticancer efficacy of the Irreversible EGFr Tyrosine Kinase Inhib PD 0169414 Against Human Tumor Xenografts", 2000, Cancer Chemother. Pharmacol. 45:231-38.	itor	

Examiner Signature	Anilone	R. Sabel	Date Considered	5/20/02
		•		

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English translation is attached.